

CHRONIC HEPATITIS C TREATMENT EXPANSION

Generic Manufacturing for Developing Countries



Gilead is working to enable access to its medicines for all people who can benefit from them, regardless of where they live or their economic means.

Snapshot

Gilead has agreements with 14 companies to manufacture generic hepatitis C medicines for **105 developing countries**

There are an estimated **71 million** people living with hepatitis C worldwide

Gilead also offers its branded hepatitis C medicines at a single, **significantly reduced price** across these countries

For more than a decade, Gilead has been working with governments, healthcare systems, providers, public health entities and generic manufacturers to make its HIV and hepatitis B medicines available worldwide. Currently, more than 10 million people living with HIV in developing countries receive Gilead antiretroviral medicines through these efforts. Gilead is also working to help ensure broad access to its hepatitis C medicines in developing countries.

Gilead has voluntary licensing agreements with 11 India-based generic pharmaceutical manufacturers to develop the hepatitis C (HCV) compounds sofosbuvir, ledipasvir, velpatasvir and voxilaprevir for distribution in 105 developing countries. Gilead also has agreements with local generic manufacturers for in-country production and distribution of our HCV medicines in Egypt and Pakistan.

Generic Agreements

Under the agreements, Gilead's generic licensees have the right to develop and market generic versions of Gilead HCV medicines in certain developing countries. The generic drug companies may set their own prices and receive a complete technology transfer of the Gilead manufacturing process, enabling them to scale up production as quickly as possible. Licensees also pay a royalty to Gilead that supports overall developing world product registration, medical education and training, safety monitoring and other business activities.



International Licensees

Aurobindo Pharma Ltd.
Biocon Limited
Cadila Healthcare Ltd.
Cipla Ltd.
Hetero Labs Ltd.
Laurus Labs Pvt. Ltd.

Mylan Laboratories Ltd.
Natco Pharma Ltd.
SeQuent Scientific Ltd.
Strides Shasun Ltd.
Sun Pharmaceuticals
Industries Ltd.

In-Country Licensees

Ferozsons Laboratories Ltd. (Pakistan)
Magic Pharma (Egypt)
Pharmed Healthcare (Egypt)

The licensing agreement encompasses the following countries:

Afghanistan	Chad	Guatemala	Maldives	Palau	Suriname
Algeria	Comoros	Guinea	Mali	Papua New Guinea	Swaziland
Angola	Congo, DR	Guinea-Bissau	Marshall Islands	Paraguay	Tajikistan
Antigua and Barbuda	Congo, Rep.	Guyana	Mauritania	Philippines	Tanzania
Bangladesh	Cook Islands	Haiti	Mauritius	Rwanda	Thailand
Belarus	Cote d'Ivoire	Honduras	Micronesia	Samoa	Timor-Leste
Benin	Cuba	India	Mongolia	Sao Tome & Pr.	Togo
Bhutan	Djibouti	Indonesia	Morocco	Senegal	Tonga
Bolivia	Dominica	Kenya	Mozambique	Seychelles	Tunisia
Botswana	Egypt	Kiribati	Myanmar	Sierra Leone	Turkmenistan
Burkina Faso	El Salvador	Kyrgyz Republic	Namibia	Solomon Islands	Tuvalu
Burundi	Equatorial Guinea	Lao PDR	Nauru	Somalia	Uganda
Cambodia	Eritrea	Lesotho	Nepal	South Africa	Ukraine
Cameroon	Ethiopia	Liberia	Nicaragua	South Sudan	Uzbekistan
Cape Verde	Fiji	Libya	Niger	Sri Lanka	Vanuatu
Central African Republic	Gabon	Madagascar	Nigeria	St. Vincent and the Grenadines	Vietnam
	Gambia	Malawi	North Korea	Sudan	Zambia
	Ghana	Malaysia	Pakistan		Zimbabwe

Chronic Hepatitis C Treatment Expansion Challenges

Providing HCV treatment in resource-limited settings presents complex challenges. For example, many countries have limited or no HCV screening, lack the healthcare infrastructure to care for significant numbers of patients and do not have the diagnostic capacity to test for the diverse range of genotypes requiring different treatment regimens. Public and policymaker awareness of the disease is limited, as is national and international funding for HCV screening and treatment.

“Curative treatments that are more efficacious and less toxic than ever before have the potential to dramatically reduce the health and economic burdens associated with HCV infection around the world. The opportunity to address the massive HCV pandemic is now within reach and a global movement is needed to create generalized access to HCV treatment in high-, middle- and low-income countries. This will require political will, financial investment, and support from pharmaceutical, medical and civil society organizations around the world.”

– WHO Guidelines for the Screening, Care and Treatment of Persons with Hepatitis C Infection, 2014

Working Locally to Advance Access

Generic manufacturing is just one component of scaling up HCV treatment. Also critical are in-country activities that support drug availability and use, including product registration, medical and clinical education, demand forecasting and collaborative research. Gilead works with a global network of regional business partners on these activities.

- **Product Registration:** Regional business partners help manage national registration processes for Gilead's branded HCV products. They also assist with pharmacovigilance and safety reporting once registrations are obtained.
- **Public Health and Medical Education:** Gilead and regional business partners conduct public health and medical education events with doctors and other healthcare providers in developing countries, to increase their knowledge of disease burden and impact, as well as viral hepatitis treatment options and their appropriate use for patients.
- **Demand Forecasting:** Ensuring an uninterrupted supply of medicine requires accurately forecasting product demand. Gilead has invested in proprietary information tools to track orders and inventory across regions and prevent disruptions in supply.
- **Collaborative Research:** National trials for sofosbuvir, ledipasvir and velpatasvir are underway or planned in several developing countries.